REMARKS

Favorable reconsideration and allowance of the claims are respectfully requested.

I. Claim Status and Amendments

Claims 1-8, 14-17, and 23-45 were pending in this application when last examined. Claims 8, 14-17, and 23-25 have been examined on the merits and stand rejected. Claims 15 and 24 have also been objected to.

Claims 1-7 and 26-45 have been withdrawn as non-elected subject matter. No claim has been allowed.

By way of the present amendment, claims 8 and 17 have been amended, in a non-narrowing manner, to address the formal matters raised in the Office Action. Support can be found in the original claims and the disclosure. See for example, paragraphs [0013], [0023] to [0031] of the corresponding published application no. 20080286309. No new matter has been added.

Claims 15 and 24 have been amended, in a non-narrowing manner, to address the formal matters raised in the Office Action. Support can be found in the disclosure, for example, for example, at paragraph [0033]. No new matter has been added.

Claims 1-8, 14-17, and 23-45 are pending upon entry of this amendment, and the examined claims define patentable

subject matter warranting their allowance for the reasons discussed herein. Applicants request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

II. Claim Objection

On page 4, claims 15 and 24 have been objected to as being in improper form for failing to further limit the claims to which they depend. The objection is traversed.

The examiner contends that claims 15 and 24 recite that the "isolated variant has the sequence as depicted in SEQ ID NO: 2 with a deletion at the C-terminal wherein an amino acid substitution is introduced". However, claims 8 and 17 from which claims 15 and 24 depend respectively, teach that the isolated variant comprises particular amino acid substitutions at particular positions. Therefore, the recitation in claims 15 and 24 "a deletion at the C-terminal wherein an amino acid substitution is introduced" does not further limit claim 15 and 24. Applicants respectfully disagree.

The present amendment renders the objection moot. Claims 15 and 24, as amended, further limit claims 8 and 17 to which they respectively depend by defining the sequence of SpaA or ΔSpaA protein in which the substitutions are introduced. This is explained at paragraphs [0024] to [0033]

of the disclosure. See for instance, paragraph [0033], wherein it is described that the amino acid sequence of SpaA or ΔSpaA protein may be the sequence as depicted in SEQ ID NO: 2 or the sequence as depicted in SEQ ID NO: 2 with deletion at its C-terminal, respectively, and it is this sequence in which the desired amino acid substitution may be introduced. By way of the present amendment, the claims have been amended, in a non-narrowing manner, to better reflect this. Thus, the objection is untenable and should be withdrawn.

III. Written Description Rejections under 35 USC 112-1st

Claims 9-10 and 18-19 have been rejected under 35 USC 112, second paragraph, for being indefinite for the reasons on pages 5-6 of the Action.

The examiner states that the claims are drawn to a genus of proteins in which any portion of the SpaA protein is deleted and which is immunogenic and also comprising the recited amino acid substitution. The examiner contends that this genus is highly variant comprising species of differing structure because any number of amino acid(s) at any location of the SpaA protein can be deleted.

At page 6, the examiner also indicates that the specification does not describe other deletion variants of a SpaA protein wherein the deletion variant further comprises the instant amino acid substitution(s) that is immunogenic.

The examiner contends that the specification does not describe the common structure, i.e. immunoepitope(s) of the genus of deletion variants of SpaA proteins further comprising the instant amino acid substitution(s) that correlates with function, i.e., immunogenicity so that one of skill in the art can envision which amino acids or combinations of amino acids can be deleted in a Spa A protein in which the remaining SpaA protein further comprises the instant amino acid substitution(s) and still retain immunogenicity. The examiner contends that disclosure of only one member of the genus to which the claims are drawn is insufficient to describe the larger genus.

Applicants respectfully disagree and submit that the instant specification provides sufficient written description support for the claims.

To start, the test for sufficiency of written description is whether the disclosure reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claimed. M.P.E.P., Eighth Ed., Rev. 7 (July 2008) at § 2163, I, 2100-159, 1st column, 2nd paragraph. This test may be satisfied by: (1) a reduction to practice; (2) a reduction to drawings/chemical formulas; (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or

chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure; (5) a sufficient description of a representative number of species; or (6) a combination of the above, sufficient to show the inventors were in possession of the invention. M.P.E.P. (Eighth Ed., Rev. 7 (July 2008) at § 2163,II, A, 3a(i)-(ii).

In the instant case, the claimed variant of SpaA protein and its shortened form, ΔSpaA protein, according to main claims 8 and 17 of the present application, are defined as an insoluble protein mutated from a soluble *Erysipelothrix rhusiopathiae* surface protective antigen SpaA or ΔSpaA protein by a specific amino acid substitution, and as a result have a property of being expressed as insoluble inclusion bodies to thereby facilitate recovery and purification of said protein. It should be noted that this property of being expressed as insoluble inclusion bodies is only possible when the specific amino acid substitution(s) as defined in the amended claims is/are introduced. This is fully described in the disclosure see for instance, paragraphs [0024] to [0033]. For example, paragraph [0033] describes that the amino acid sequence of SpaA or ΔSpaA protein may be the sequence as depicted in SEQ ID NO: 2 or the sequence as depicted in SEQ ID NO: 2 with

deletion at its C-terminal, respectively, and it is this sequence in which the desired amino acid substitution may be introduced. This clearly provides for a relevant identifying characteristics, such as structure (i.e., the structure of the amino acid sequence). Further, contrary to the examiner's position, the claims do not relate to any number of amino acid(s) at any location of the SpaA protein can be deleted. Instead, the claims specify that the specific substations in this sequence are needed in order to result in the specifically recited functional properties. This amounts to a sufficient description of functional characteristics coupled with a known or disclosed correlation between function. In this regard, the specific substitutions, as claimed and as described in the disclosure, are as follows:

(1) the 69th amino acid from the N-terminal encompassing the signal sequence is substituted with glycine;

(2) the 154th amino acid from the N-terminal encompassing the signal sequence is substituted with glycine;

(3) the 203rd amino acid from the N-terminal encompassing the signal sequence is substituted with threonine;

(4) the 214th amino acid from the N-terminal encompassing the signal sequence is substituted with glutamine;

(5) the 253rd amino acid from the N-terminal encompassing the signal sequence is substituted with threonine;

(6) the 278th amino acid from the N-terminal encompassing the signal sequence is substituted with glycine; and

(7) the 531st amino acid from the N-terminal encompassing the signal sequence is substituted with glycine.

Again, the specification clearly teaches that the property of being expressed as insoluble inclusion bodies is only possible when one or more of the above noted specific amino acid substitution(s) are introduced. This clearly provides for a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties (i.e., the specific substitutions in the specific amino acid sequence), as well as functional characteristics coupled with a known or disclosed correlation between function (the property of being expressed as insoluble inclusion bodies) and structure.

Further, the specification, at for example, paragraph [0067], teaches a ΔSpaA protein encoded by a partial SpaA gene up till the 1260th nucleotide and codes for a shortened form of SpaA protein (with deletion of 207 amino acid residues at the C-terminal) with particular amino acid substitutions at particular positions, and that this was found to be immunogenic.

In addition, the specification at paragraphs [0073] and [0074] teaches that the region and size of ΔSpaA protein, obtained by deletion of a portion of SpaA protein, is not subject to restriction insofar as ΔSpaA protein remains immunogenic and, when amino acid substitution is introduced, is capable of forming inclusion bodies. The specification even teaches that the ΔSpaA protein can have at least about 1/3 of the C-terminal of SpaA protein deleted and still be used in the present invention. The specification also indicates that preferably, the ΔSpaA protein comprises 420 amino acid residues from the N-terminal encompassing the signal sequence with deletion of 207 amino acids at the C-terminal. It is respectfully submitted that this disclosure clearly identifies where and to what extent the deletion of the SpaA protein should be in order to obtain the ΔSpaA protein of the claims. Thus, contrary to the examiner's position at page 6 of the Office Action, the present invention is not drawn to a broad genus of proteins in which any portion of the SpaA protein is deleted and which is immunogenic and also comprising the recited amino acid substitution. Again, the specification clearly identifies the location and amount of the deletions the which are required (upto 1/3 of the C-terminal of SpaA protein), as well as, the specific amino acid

sequence of the SpaA protein (SEQ ID NO: 2), and it identifies the specific mutations in this sequence.

In view of the above, it is respectfully submitted that the specification at least provides: a reduction to practice; a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; and a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to show the Applicants were in possession of the invention. In addition, the numerous peptides described above and discussed in the specification constitute a sufficient description of a representative number of species sufficient to show the inventors were in possession of the claimed invention.

Therefore, Applicants respectfully submit that the specification provides full written description support for claims. For these reasons, the above written description rejection is believed to be untenable and should be withdrawn.

IV. Indefiniteness rejections under 35 USC 112-2nd

Claims 8, 14-17, and 23-25 have been rejected under 35 USC 112, second paragraph, for being indefinite for the reasons on pages 8-9 of the Action.

The present amendment renders the rejection moot. In particular, the claims, as amended, specify an isolated variant of an Erysipelothrix rhusiopathiae surface protective antigen SpaA protein or of a shortened form thereof (known as ΔSpaA protein), which is a shortened form of the SpaA protein in which a portion of the SpaA protein is deleted, and the amended claims make it clear that both variants have the specifically recited substitutions therein such that both have the specific properties of being immunogenic and being expressed as inclusion bodies. The amended claims makes it clear that the specific substitutions therein and the resultant properties refer to both the variant of the SpaA protein and the variant of the ΔSpaA protein, as is consistent with the disclosure, for example, at paragraph [0013].

Thus, the amended claims are believed to be clear and definite. It is believed that the present amendment renders the rejection moot. Thus, withdrawal of the rejection is respectfully requested.

V. Prior are rejection

Claims 8, 15-17, 24, and 25 have been rejected under 35 USC 102(b) as being anticipated by Fischetti et al. (WO 00/47744) for the reasons on pages 10-12.

This rejection is respectfully traversed. The rejection should fall, because the cited reference fails to

disclose each and every element of claims 8 and 17, which are the independent claims in this application.

Specifically, as noted above, claims 8 and 17, as amended, specify an isolated variant of an Erysipelothrix rhusiopathiae surface protective antigen SpaA protein or of a shortened form thereof (known as ΔSpaA protein), which is a shortened form of the SpaA protein in which a portion of the SpaA protein is deleted, and the amended claims make it clear that both variants have the specifically recited substitutions therein such that both have the specific properties of being immunogenic and being capable of being expressed as inclusion bodies. The amended claims makes it clear that the specific substitutions therein and the resultant properties refer to both the variant of the SpaA protein and the variant of the ΔSpaA protein, as is consistent with the disclosure, for example, at paragraph [0013]. It is believed that Fischetti et al. fails to disclose or suggest such a variant as claimed in the claims 8 and 17.

The examiner argues that Fischetti et al., at page 9, lines 27-30 and at page 10, lines 10-22, discloses functional conservative variants. However, nowhere does Fischetti et al. disclose or suggest the specific substitutions, as recited in the claims.

Further, the claimed variant of SpaA protein and its shortened form, ΔSpaA protein, according to claims 8 and 17 of the present application, are defined as an insoluble protein mutated from a soluble *Erysipelothrix rhusiopathiae* surface protective antigen SpaA or ΔSpaA protein by specific amino acid substitution (page 13, lines 10-15), and have a property of being expressed as insoluble inclusion bodies (as recited in the claims) to thereby facilitate recovery and purification of said protein. The examiner argues that this is a process limitation and as such it is given no patentable weight. Applicants disagree. It should be noted that this property of being expressed as insoluble inclusion bodies is only possible when the specific amino acid substitution(s) as defined in the claims is/are introduced. As such, it is believed that the specific substitutions, as claimed, impart a structural property on the claimed variant, that is not taught in the prior art. Again, Fischetti et al. does not disclose or suggest this.

Therefore, it should be clear that the cited Fischetti et al. fails to disclose each and every element of claims 8 and 17. It is well established that to anticipate a claim, a cited prior art reference must disclose or suggest each and every element of the claimed invention. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2

USPQ2d 1051, 1053 (Fed. Cir. 1987); and M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2131.

Therefore, claims 8 and 17, and all claims dependent thereon, are believed to novel over the cited reference. Withdrawal of the anticipation rejections is requested.

Further, Applicants believe that there is no reason/suggestion in Fischetti et al. to make the noted substitutions, as recited in the claims. Thus, it is believed that the claims, as amended, would never have been obvious to one of ordinary skill in the art, upon reading the cited prior art references. For these reasons, claims 8 and 17, and all claims dependent thereon, are believed to novel and non-obvious over Fischetti et al.

VI. Conclusion

Applicants believe that all issues raised in the Office Action have been fully addressed in a manner that should lead to patentability of the present application. Favorable consideration and allowance are respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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